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DAVIS & BUJOLD, P.L.L.C.
112 PLEASANT STREET
CONCORD, NH 03301

EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,305	DAVENPORT ET AL.	
	Examiner	Art Unit	
	CLINTON T. OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,13-42 and 44* is/are pending in the application.

4a) Of the above claim(s) *20-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13-19 and 44* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☒ Claim(s) *1,3-11,13-42 and 44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the Amendment filed June 13, 2011, and the Supplemental Amendment filed July 27, 2011. As directed by the amendment filed June 13, 2011, claims 1, 7, 10-11, 17, 36 and 44 have been amended; claims 20-42 have been withdrawn from consideration and claims 2, 12, and 43 have been cancelled. As directed by the Supplemental Amendment filed July June 27, 2011, claims 1, 11, 19 and 44 have been amended; claims 20-42 have been withdrawn from consideration and claims 2, 12, and 43 have been cancelled. Thus, claims 1, 3-11, 13-42, and 44 are pending in this application with claims 20-42 being withdrawn from consideration. Therefore, claims 1 and 3-11, 13-19 and 44 are presented for examination on the merits.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2011 and July 27, 2011 have been entered.

Election/Restrictions

3. This application contains claims 20-42 drawn to an invention nonelected without traverse in the reply filed on October 23, 2009. A complete reply to the final rejection

mailed January 13, 2011, should have included a cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

4. Claim 1 is objected to because of the following informalities:

Claim 1 is objected to because it appears the term “insert” in line14 should be “inserted”. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3-10 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Where a claim is directed to an apparatus attached to the human body or any part thereof the claim is directed to nonstatutory subject matter because the claim positively recites part of a human body. See: 1077 Official Gazette, April 21, 1987.

Claims 1 is rejected because it positively recites parts of a human body to claim the apparatus. Claim 1 claims “the pair of supply lines being connected with one

another by **a central bridge member having an axial length that spans no more than a width of a philtrum of the patient**." Emphasis added.

Claim 44 is rejected because it positively recites parts of a human body to claim the apparatus. Claim 44 recites a the cylindrical section having a **cylindrical exterior surface of which has a maximum outside diameter that is slightly larger than an interior diameter of a nasal cavity of the patient** in which the head is to be received so that each head is sized to be snugly received and retained within one of the nasal cavities of the patient **the exterior surface of the head has a plurality elongate troughs formed therein so as to defined with a portion of inwardly facing nasal cavity skin the patient** a plurality of leakage passages which facilitate exhausting of excess respiratory gas through the leakage passages while maintaining a positive pressure within a respiratory passage of the patient at least during exhalation by the patient."

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-10, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 44 use a human, or parts thereof, to define a device. The metes and bounds of the claimed device are unascertainable since the same exact claimed

device may be encompasses by the claimed limitations on one patient, but not be encompassed by a second patient. That is, patient, including humans, vary in size with age, sex, ethnicity, etc. Therefore, the metes and bounds of the claim are unascertainable since they would vary based on the specific patient population using the device.

Any remaining claims are rejected as depending from a rejected base claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payton (4,660,555) in view of Kahn (5,105,807); and further in view of Rittmann (6,270,521).

Regarding claims 1 and 11, Payton discloses a nasal cannula (figures 1 and 10-12) for supplying a respiratory gas (oxygen) to a patient, the nasal cannula comprising a supply line (41) which has a head (conical end 42) adjacent a leading end (distal end) thereof with a discharge opening (24a) therein for discharging a respiratory gas (oxygen), and an opposite end (distal end) of the supply line (41) being connectable (capable of being connected) to a respiratory gas source (via 36); wherein the head (42) is formed integrally with and from the same material as the pair of supply line (col. 5,

lines 36-40) and each head is sized to be snugly received and retained within one of the nasal cavities of the patient (figure 1), an exterior surface of the head (42) has a plurality elongate troughs (45) formed therein, and the plurality elongate troughs (45) form, once insert into the respective nasal cavity, a plurality of leakage passages (passages allow for gas in or out), between a portion of inwardly facing nasal cavity skin of the patient (figure 1) and the plurality elongate troughs (45) of the head (42), to facilitate exhausting of excess respiratory gas supplied to the patient through the leakage passage (45) while maintaining a positive pressure (via air supplied to the nasal passages via 36 to the cone shape (42) of the device shown in figures 10-12 and the interaction with the interior of the patients nasal cavities as shown in figure 1) within a respiratory passage of the patient at least during exhalation by the patient (gas is allowed to enter the nasal passages via 45 and 20a but would be exhaled through the passages 45 in the device shown in figures 10-12; thus, a positive pressure would inherently be created as the patient exhales from the nasal passages). See: figures 1 and 10-12 and col. 5, lines 9-40.

However, Payton lacks a device that comprises a head with a leading tapered section and a trailing tapered section wherein the generally cylindrical section has a generally cylindrical surface with elongate troughs extending parallel to one another and a pair of supply lines with each supply line having a head, wherein the pair of supply lines is connected with one another by a central bridge member having an axial length that spans no more than a width of a philtrum of a patient.

Kahn teaches a disposable nasal anchoring system with various shapes that can be used as a compressible sleeve and that modifications of the sleeve can be adapted according to need or desirability. See: col. 3, lines 38-46 and figures 4a-4g. Kahn specifically teaches a head (figure 4g) that has a generally cylindrical surface with elongate troughs extending parallel to one another. Kahn specifically teaches that the exterior surface of the head taught in figure 4g of Kahn has between six and eight elongate troughs (formed between ridges) formed therein which are equally spaced about a circumference of the head, and each of the elongate troughs partially defines one of the leakage passages in the head to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g.

Rittmann teaches a device comprising a pair of supply lines (20) with each supply line having a head (21) with a leading tapered section and a trailing tapered section, wherein the pair of supply lines is connected with one another by a central bridge member (connecting tubes 20 to one another in figure 10) which has an axial length that spans no more than a width of a philtrum of a patient (which would depend on the patient the device was used upon).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the oxygen delivery system disclosed by Payton, by using a generally cylindrical shaped nasal insert with troughs, as taught by Kahn, and used a system with heads that are tapered and delivers oxygen to both nostrils of a patient, as taught by Rittmann, in order to provide an oxygen delivery device that deliver

supplemental oxygen to a both nasal airways of a patient with sculptured heads that would be more comfortable to wear, thereby enhancing the delivery of supplemental oxygen, increasing comfortability of the user over long periods of use, simultaneously allowing for passage of air through the device in case of mechanical failure of the supplemental oxygen delivery system.

Regarding claims 3 and 13, Kahn teaches that the exterior surface of the head taught in figure 4g of Kahn has between six and eight elongate troughs (formed between ridges) formed therein which are equally spaced about a circumference of the head, and each of the elongate troughs partially defines one of the leakage passages in the head to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient. See: col. 5, lines 29-43 and figure 4g.

Regarding claims 4 and 14, each of the plurality elongate troughs of Kahn is formed by a pair of adjacent planar side surfaces (sides of exterior walls) which diverge away from a common elongate valley (lowest most point of troughs) toward a pair of spaced apart but adjacent elongate ridges (upper most point of exterior surfaces) to partially define one of the plurality of leakage passages. See: col. 5, lines 29-43 and figure 4g.

Regarding claims 5-6 & 15-16, the combined references lack the specific teaching that each one of the leakage passages has a cross sectional open area of between about 0.002 square inches (0.013 cm2) and 0.0055 square inches (0.035 cm2), as claimed in claim 5; or, wherein each head has a maximum width dimension of between about 0.345 of an inch (0.88 cm) about 0.70 of an inch (1.8 cm) and a length of

between about 0.30 of an inch (0.76 cm) and about 0.60 of an inch (1.5 cm); however, Kahn specifically describes how modifications of the sleeve can be adapted according to need or desirability and it a change in the size or shape of a prior art device is a design consideration well within the skill of the art.

Regarding claim 7, the upper surface of the central bridge member (connecting tubes 20 in figure 10 of Rittmann) is rounded, which would avoid any sharp edge that may contact with a nasal septum of the patient.

Regarding claims 8 and 18, the device of the combined references discloses a nasal cannula with supply lines (41 of Payton) and the heads (42 of Payton modified by the shape of the head Figure 4g of Kahn with the tapered ends of Rittmann) that are manufactured from a flexible material (col. 5, lines 36-40 of Payton) and the second end of each of the supply lines bends (41 is an elbow and by placing the device in the clip of Rittmann) they would bend away from one another.

Regarding claim 9 and 19, the nasal cannula of the combined references has a second end (distal end of 41 of Payton) of each of the supply lines (41 of Payton) is coupled to an auxiliary respiratory gas supply line (36 of Payton which corresponds to 5 of Kahn and 20 of Rittmann) and at least the second end of each of the supply lines is curved to pass beneath a patient's cheekbone area when the nasal cannula is donned by a patient. See: figure 1 of Payton. With regard to claim 19, the amendment, which is unclear, but adds the additional feature wherein the “head defines an through aperture, radially spaced from an interior of the supply line and parallel to and spaced from the to the plurality of elongate troughs,” as can be seen in the structure of figure 4 of Kahn, the

generally cylindrical shaped head has six to eight troughs. Thus, if the plurality of troughs of claim 1 were two troughs, any one of the remaining troughs four to six troughs meets this limitation.

Regarding claim 10, the nasal cannula of the combined references discloses a central bridge member (middle portion of the device connecting tubes 20 to one another in figure 10 of Rittmann) aligns the pair of supply lines (20 of Rittmann) parallel to one another (when nasal cannulas of Payton are placed into the device connecting tubes 20 to one another in figure 10 of Rittmann) to facilitate insertion of the heads (42 of Payton), carried by the ridge (40 of Payton) of the pair of supply lines (41 of Payton), within the nostrils of the patient and the supply lines initially extend away from the central bridge member. See: figure 1 of Payton and figure 10 of Rittmann. However, the combined references lack the specific teaching that the supply lines then bend into a curved configuration having a radius of curvature of between about 0.4 inch to about 0.8 inch which creates a minimal pressure drop, turbulence and noise generation at a maximum flow rate. However, Payton specifically shows the supply lines curving up and around the patients ears and modifications of the curvature of the supply lines would be easily modified according to need or desirability of a patient during use and it a change in the shape of a prior art device is a design consideration well within the skill of the art.

10. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payton (4,660,555) in view of Kahn (5,105,807) and Rittmann (6,270,521); and further in view of Zimmerman (4,273,124).

The combined references disclose all the limitations of claims 17 and 44, except the central bridge member being formed integral with and from the same material as the supply lines and the heads.

Zimmerman teaches nasal inserts may be formed integrally with gas supply lines (figure 2) or they can be joined together as separate components (figure 4) and specifically teaches a dual nasal insert with a connecting bridge member (figure 7). See: col. 3, lines 45-53 and col. 5, lines 15-24. Thus, forming of a one piece construction instead of separate components would be merely a matter of an obvious engineering choice to one having ordinary skill in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nasal cannula of the combined references, by forming the device into integrally, as taught by Zimmerman, because of the reasonable expectation that a skilled artisan would ready recognize that the device could be formed as a one piece construction instead of separate components as this would be merely a matter of an obvious engineering choice to one having ordinary skill in the art. Moreover, a device formed integrally from a single material would be reasonably expected to perform equally as well as a device formed of separate components connected together.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3-11, 13-19 and 44 have been considered but are moot in view of the new ground(s) of rejection.

Remarks

12. Claim 19 appears to be an attempt by applicant to claim the features of figure 12A, which were discussed during the telephonic interview. However, the current claim language is unclear and continues to read on the prior art as discussed above. However, if applicant would like to discuss claim language that would distinguish the claims from the prior art (i.e. what is shown in figures 12A & 12B), the examiner encourages applicant to contact the examiner.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON T. OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CLINTON T. OSTRUP/
Examiner, Art Unit 3771